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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/784,829

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EXAMINER

SMITH, RUTH S

ART UNIT

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3737

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/784,829	Applicant(s) UHL ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-97 and 99-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 and 62-64 is/are allowed.
- 6) ☒ Claim(s) 19-61 and 65-97, 99-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/08, 11/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-30,38-40,46-48,51,52,55-56,59-61,66,67,69-72 rejected under 35 U.S.C. 102(e) as being anticipated by Allen (4,945,914). Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical markers or fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located/tracked using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series two-dimensional slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-33,49,50,87-97,103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (4,945,914) in view of Strohl Jr. et al or Van Steenwyk et al. Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical markers or fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series of two-dimensional slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer. Allen fails to disclose the use of electromagnetic tracking means for tracking the position of the markers/instrument. Strohl et al and Van Steenwyk et al disclose the use of electromagnetic tracking means for tracking the location of a device. It would have been obvious to one skilled in the art to have modified Allen such that the means for tracking the position of the markers is an electromagnetic tracking device. Such a modification merely involves the substitution of one known type of tracking device for another. Furthermore, it would have been obvious to one skilled in the art to use the locating device to track the position of the surgical instrument in order to properly align it with respect to the body for treatment as taught by Strohl et al and Steenwyk et al.

Claims 99-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen ('914) in view of Strohl Jr. et al or Van Steenwyk et al as applied to claim 87

above, and further in view of Codrington. Codrington discloses a medical imaging system with a catheter where the position of the catheter is displayed in real-time on the images provided. It would have been obvious to one skilled in the art to have further modified Allen such that the position of the treatment device is shown in the image reference frame in order to allow the operator to know if it is properly aligned with respect to the target.

Claims 34-37,41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (4,945,914) in view of Lewin. Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical markers or fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series two-dimensional slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer. Allen fails to disclose the use of optical tracking means for tracking the position of the markers. Lewin disclose the use of optical tracking means for tracking the location of a device. It would have been obvious to one skilled in the art to have modified Allen such that the means for tracking the position of the markers is an optical tracking device. Such a modification merely involves the substitution of one known type of tracking device for another. In the absence of any showing of criticality, the specific type of optical tracking means used would have been an obvious design choice of known equivalents in the art.

Claims 44,45,53,57,58,65,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen ('914). Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical

markers are fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series two-dimensional slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer. Allen fails to disclose the use of a graphical tool to identify the base points in the image data. The system of Allen inherently includes means to identify the base points in the image. In the absence of any showing of criticality, the specific means used to identify the base points in the image would have been an obvious design choice of known equivalents in the art. With respect to claims 53,57,58, in the absence of any showing of criticality, the specific form of the information displayed regarding the target location and the direction of intervention would have been an obvious design choice of known equivalents in the art. With respect to claim 65, in the absence of any showing of criticality, the specific type of data provided would have been an obvious design choice of known equivalents in the art. With respect to claim 68, Allen discloses that the patient remain fixed with respect to the scanner. It would have been obvious to one skilled in the art to have fixed the head set to the operating table in order to prevent the patient from moving with respect to the scanner.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen ('914) in view of Codrington. Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical markers are fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series two-dimensional

slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer. Allen fails to disclose the use providing a real-time display of the surgical instrument. Codrington discloses a medical imaging system with a catheter where the position of the catheter is displayed in real-time on the images provided. It would have been obvious to one skilled in the art to have modified Allen such that the position of the treatment device is shown in the image reference frame in order to allow the operator to know if it is properly aligned with respect to the target.

Claims 73-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen ('914) in view of Codrington and Strohl Jr. et al or Van Steenwyk et al. Allen discloses an interactive system and method that includes using fiducial markers to identify a patient reference frame and images of those markers to define an image reference frame. The markers can either be anatomical markers or fiducial markers implanted in the body. Surgical intervention can be carried out after a target is located using the markers and images. The surgery can be robotically controlled and can include radiation or laser therapy. The markers can be located using a metal detector, ultrasonic detector or any instrument that can sense the position of the implant in the body. The images obtained are a series two-dimensional slices that include the volume of the tumor therefore providing three dimensional information. The computer used can either be the computer that is part of the existing scanning system or a stand-alone computer. Allen fails to disclose determining the position of the surgical instrument and displaying its position in the image reference frame. Allen also fails to disclose the use of electromagnetic tracking means for tracking the position of the markers/instrument. Strohl et al and Van Steenwyk et al disclose the use of electromagnetic tracking means for tracking the location of a device. It would have been obvious to one skilled in the art to have modified Allen such that the means for tracking the position of the markers is an electromagnetic tracking device. Such a modification merely involves the substitution of one known type of tracking device for another. Furthermore, it would have been obvious to one skilled in the art to use the locating device to track the position of the

surgical instrument in order to properly align it with respect to the body for treatment as taught by Strohl et al and Steenwyk et al. Codrington discloses a medical imaging system with a catheter where the position of the catheter is detected and displayed in real-time on the images provided. It would have been obvious to one skilled in the art to have further modified Allen such that the position of the treatment device is shown in the image reference frame in order to allow the operator to know if it is properly aligned with respect to the target.

Allowable Subject Matter

Claims 1-16,62-64 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed 11/10/06 have been fully considered but they are not persuasive. Claim 19 was not amended to include the limitations of previous claim 98. Claim 19 was amended to include a tracking system. Allen discloses means for locating/tracking the position of the markers and therefore the claimed invention does not define over Allen. The markers provide the second reference structure, therefore, Allen does disclose a tracking system for determining a position of the markers. Applicant's arguments regarding Codrington are noted, however, the arguments do not appear to be directed to claimed limitations. Applicant continues to argue that the references require continuous imaging to track the position of an instrument. It should be noted that the claims fail to preclude the use of continuous imaging.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS